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EXAMINER

ROLLINS, ROSILAND STACIE

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 02/06/2004

18

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/770,603

Applicant(s)

SCHWARTZ, ARTHUR E.

Examiner

Rosiland S Rollins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20-32 and 47-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-32 and 47-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 33-37 been renumbered 47-53.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-28, 30, 31, 47-51 and 53 continue to be rejected under 35 U.S.C. 102(b) as being anticipated by Saab (5,624,392). Saab shows a catheter (10) for intravascular corporeal cooling comprising: an elongated tubular member (12) having proximal and distal sections, an outer surface, and at least one lumen (11) extending therethrough, and annular insulation (16, 22) having proximal and distal ends arranged concentrically (Fig. 1) around the outer surface of the elongated tubular member (12) is insulated from fluid or tissue external to the annular insulation (16, 22), wherein the insulation is tapered (at 18), extends along substantially the whole length or a shorter section of the catheter (col 16, lines 54-59) and comprises a fluid-filled

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member, filled with gas, water or saline (col 9, line 66 - col 10 line 2) and polymeric material (14, 20, col 10, lines 38-39). Regarding claim 30, the structure can be used for brain cooling.

Claims 20-24, 27, 30-32, 47-50 and 53 continue to be rejected under 35 U.S.C. 102(e) as being anticipated by Ginsburg (6,033,383). Ginsburg shows a catheter for intravascular corporeal cooling comprising: an elongated tubular member (20) having proximal (24) and distal (26) sections, an outer surface, and at least one lumen (28) extending therethrough, and annular insulation (18, 32, 34) having proximal and distal ends arranged concentrically (Fig. 2) around the outer surface of the elongated tubular member (20) is insulated from fluid or tissue external to the annular insulation (col 6, lines 6-13), wherein the insulation is tapered (Fig. 11) and comprises a fluid-filled member, and at least one lumen is in communication with a source of cooled blood and/or a liquid pharmaceutical source (col 4, lines 1-13), which can be used for brain cooling (col 4, line 9).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg in view of Donlon (6,056,723). Ginsburg shows all of the limitations of

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claim 29 except for the pressure sensor. Donlon shows a similar catheter for placement in a blood vessel, which includes a pressure sensor (38). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a pressure sensor in the device of Ginsburg to prevent injury by which can be caused by high pressure fluids in the bloodstream.

### ***Response to Arguments***

1. Applicant's arguments filed 1/2/04 have been fully considered but they are not persuasive.

Applicant argues that "Saab requires materials with good heat transfer properties to allow the temperature of the fluid inside the catheter to be transferred to adjacent portions of the body that are in contact with or in proximity to the catheter sidewalls. In essence Applicant is indicating that Saab does not insulate the portion of the body in contact with or in proximity to the catheter side walls from the temperature of the fluid passing through the tubular member (12). In column 9 lines 41-45 Saab states that ". . . fresh heat transfer fluid at a desired temperature ordinarily (but not necessarily) different from normal body temperature . . . passes through inlet fluid lumen to the distal end of the sleeve . . .". The statement that the temperature of the fluid is not necessarily different from that of the normal body temperature indicates that by maintaining the body portion in contact with the catheter at normal body temperature, the fluid is in fact

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insulating the body portion from the temperature of the fluid passing through tubular member (12).

Regarding the argument that Saab teaches a closed loop system and specifically teaches against a system where any portion of the fluid could remain in the body, please refer to column 8 lines 28-30 where Saab discloses an open loop system.

In response to the argument Ginsburg does not provide insulation to prevent the temperature of the blood passing through the catheter lumen from being altered. In column 6 lines 8-9 Ginsburg teaches that the temperature of the outer surface of the catheter does not change which inherently forms an insulation barrier for the body portion in contact with outer surface of the catheter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosiland S Rollins whose telephone number is 703/3082711. The examiner can normally be reached on Mon.-Fri. 9:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 703/3080994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Rosiland S Rollins  
Primary Examiner  
Art Unit 3739

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